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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,733	03/14/2006	Patricia Imbach	33371-US-PCT	7768

75074 7590 11/10/2008

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EXAMINER	
STONE, CHRISTOPHER R	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
11/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,733	IMBACH ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER R. STONE	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed July 31, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of non-Hodgkin's lymphoma (NHL), does not reasonably provide enablement for the prevention of NHL, or the prevention or treatment of all conditions susceptible to treatment with an ALK inhibiting agent, defined to include at least, all proliferative disease, all hematological disease, and all neoplastic disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 1-8 are drawn to a method of treating all conditions susceptible to treatment with an ALK inhibiting agent, defined to include at least, all proliferative disease, all hematological disease, and all neoplastic disease. The prior art teaches that the treatment of said diseases is difficult. For instance, the prior art indicates that neoplastic disease is a group of maladies not treatable or preventable with one medicament or therapeutic regime. No single chemotherapeutic drug is useful for the treatment of every case of cancer. In fact, some types of cancer do not respond well to any known chemotherapeutic drugs (see Oxford Textbook of Oncology, p. 451, Column 2, last paragraph). These negative results indicate the unpredictability of the art. Furthermore, the applicant has provided no working examples demonstrating the efficacy of this method for the prevention of any condition. The Applicant has only provided a working example demonstrating the ability of said method to treat NHL. For these reasons, it would take undue experimentation by one of ordinary skill in the art to use this method to prevent all proliferative disease, all hematological disease, and all neoplastic disease, or to treat all proliferative disease, all hematological disease, and all neoplastic disease, other that NHL, with a reasonable expectation of success.

Applicant argues that the in vivo results, i.e. the ALK tyrosine kinase inhibitory activity, correlate to the claimed method of invention. This is found unpersuasive. As the applicant points out, in vitro data may be sufficient if there is a reasonable correlation between the disclosed in vitro utility and the claimed in vivo activity. In the instant case there is not a reasonable correlation between the narrow disclosure in the specification (e.g. discussion of mechanism and in vitro experimentation with a single cell line) and

the extremely broad scope of the claimed subject matter (i.e. the treatment of all conditions susceptible to treatment with an ALK inhibiting agent, defined to include at least, all proliferative disease, all hematological disease, and all neoplastic disease). The courts have held ".. in cases involving predictable factors, such a s mechanical or electrical elements, a single embodiment provide broad enablement in the sense that once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictably of factors involved." (*In re Fisher* 166 USPQ 18 (CCPA)). With the exception of NHL, neither the art or the teachings of the specification identify those plethora of conditions associated with aberrant ALK activity. One skilled in the art would have to first identify the conditions associated with aberrant ALK activity and then test to see if they respond to the claimed chemical compounds. As previously set forth, the conditions have disparate etiologies and Applicants have not demonstrated that they are linked by aberrant ALK activity. Applicant has not identified the genus of conditions associated with aberrant ALK activity, but merely invites the skilled artisan into further experimentation to obtain such. Also see Enzo Biochem Inc. v. Calgene Inc. 52 USPQ2d 1129 (CAFC 1999). "A recurring problem is whether a specification that sets forth a single or a limited number of examples can be enabling of broad claims when the subject matter concerns biological materials or reactions which are generally considered to be unpredictable." (Page 1138) Given the relative incomplete understanding in the

biotechnological field involved, and the lack of a reasonable correlation between the narrow disclosure in the specification and the broad scope of protection sought in the claims, a rejection under 35 USC 112, first paragraph for lack of enablement was appropriate.

One of ordinary skill in the art would not expect a reasonable correlation between the narrow disclosure and the broad instantly claimed methods because of the tremendous unpredictability of the art, as evidenced by the reference cited above. For these reasons, it would take undue burden by one of ordinary skill in the art to practice the treatment of any condition susceptible to treatment with an ALK inhibiting agent, defined to include at least, all proliferative disease, all hematological disease, and all neoplastic disease, using the instantly claimed method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application

filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Baenteli et al (WO 03/078404, listed on PTO 1449).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Baenteli et al discloses the use of the elected species of compound for the treatment of non-Hodgkin's lymphoma (NHL), defined on pages 1 and 24 of the specification as proliferative, hematological and neoplastic disease, associated with the expression of the NPM-ALK gene fusion (p. 12, Table 2, Example 56). Baenteli et al additionally demonstrates the ability of said compound to inhibit T-cell activation and proliferation (Example 2, p. 23). Baenteli et al does not teach that the efficacy of the treatment is due to the ALK (or ALK gene fusion) inhibitory effect of the compound, but this activity is a property of the compound and is necessarily present. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe

inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Applicant argues that Baenteli et al does not disclose a method of treating a condition susceptible to treatment with an ALK inhibiting agent. This is not found persuasive because, as noted above, Baenteli et al the instantly claimed active steps of administering the elected species of compound to the instantly claimed patient population (i.e. a patient with NHL) and products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstances or, in the present case, to the same patients. Please reference MPEP §2112. Preamble language in claims of patents directed to administration of drugs are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims, see Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). In the instant case, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Additionally, Applicant is reminded that an inherent feature (i.e. ALK inhibitory activity), need not be recognized at the time of invention (see MPEP 2112, II).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

04November2008

CRS

/Patricia A. Duffy/

Primary Examiner, Art Unit 1645